

**PATENT** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	George Mulligan et al.			
Application No.:	10/728,055	Group No.:	1642	
Filed:	December 4, 2003	Examiner:	Reddig, Peter J.	
For:	METHODS FOR THE IDENTIFICATION, ASSESSMENT, PREVENTION AND			
	TREATMENT OF PATIENTS WITH PROTEASOME INHIBITION THERAPY			

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

# IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed:

(x) Within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

#### OR

[] After three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but before the mailing date of either:

# CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\*

I hereby certify that, on the date shown below, this correspondence is being:

#### **MAILING**

deposited with the United States Postal Service in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10\*

with sufficient postage as first class mail. 

as "Express Mail I Mailing Label No.

as "Express Mail Post Office to Address" Mailing Label No.

TRANSMISSION

transmitted by facsimile to the Patent and Trademark Office.

Signature

Sean Hunziker/Beverly Sotiropoulos

ate: October 23, 2006 (type or print name of person certifying)

\*WARNING:Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b). "Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

- (1) a final action under Section 1.113,
- (2) a notice of allowance under Section 1.311, or
- (3) an action that otherwise closes prosecution in the application

whichever occurs first.	
() Accompanying this transmittal is the fee set forth in 37 information disclosure statement under Section 1.97(c). (\$18	
() Each item of information contained in the information communication from a foreign patent office in a counterpart months prior to the filing of the information disclosure states	art foreign application not more than three
() No item of information contained in the information decommunication from a foreign patent office in a counterpark knowledge of the person signing the statement after making individual designated in Section 1.56(c) more than three medisclosure statement. 37 C.F.R. Section 1.97(e)(2).	rt foreign application and to the greasonable inquiry, was known to any
OR	
() The information disclosure statement transmitted hereves Section 1.113, or a notice of allowance under Section 1.3 simultaneously with, the payment of the issue fee.	
( ) In accordance with the requirements of 37 C.F.R. Sectio	n 1.97(d):
A. [] Accompanying this transmittal is the fee submission of an information disclosure statement	e set forth in 37 C.F.R. Section 1.17(p) for ent under Section 1.97(c). (\$180.00).
B. () Each item of information contained in the in a communication from a foreign patent office in a cothree months prior to the filing of the information 1.97(e)(1).	• • • • • • • • • • • • • • • • • • • •
C. [] No item of information contained in the in a communication from a foreign patent office in a knowledge of the person signing the statement after maindividual designated in Section 1.56(c) more than information disclosure statement. 37 C.F.R. Section 1.97	king reasonable inquiry, was known to any three months prior to the filing of the

# **FEE PAYMENT**

3. () The fee due is set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

[ ] A duplicate of this request is attached.

If any additional fees are due, please charge Account 501668.

October 23, 2006	MILLENNIUM PHARMACEUTICALS, INC.
·	By Ju M. porment
	Trace M. Sioussat, Ph.D.
	Registration No. 50,609
	40 Landsdowne Street
	Cambridge, MA 02139
	Telephone - 617-374-7679
	Facsimile - 617-551-8820

**PATENT** 

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	George Mulligan et al.			
Application No.:	10/728,055	Group No.:	1642	
Filed:	December 4, 2003	Examiner:	Reddig, Peter J.	
For:	METHODS FOR THE IDENTIFICATION, ASSESSMENT, PREVENTION AND			
	TREATMENT OF PATIENTS WITH PROTEASOME INHIBITION THERAPY			

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### INFORMATION DISCLOSURE STATEMENT

### **List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

- 1. (x) Preliminary Statements
- 2. (x) Form PTO/SB/08B (1 page)
- 3. (x) Copy of Listed Information Item(s) Accompanying This Statement
- 4. (x) Identification of Person(s) Making This Information Disclosure Statement

#### Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty

# CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\*

I hereby certify that, on the date shown below, this correspondence is being:

#### MAILING

deposited with the United States Postal Service in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

#### 37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10\*

with sufficient postage as first class mail.

as "Express Mail Post Office to Address" Mailing Label No.

TRANSMISSION

transmitted by facsimile to the Patent and Trademark Office.

Signature

Sean Hunziker/Beverly Sotiropoulos

Date: October 23, 2006

(type or print name of person certifying)

\*WARNING: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b). "Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

# Section 2. Copies of Listed Information Items Accompanying This Statement

Legible copies of all relevant portions of items listed in Form PTO/SB/08B (substitute for Form PTO-1449) (references C1-C9) accompany this information statement.

October 23, 2006

MILLENNIUM PHARMACEUTICALS, INC.

Tracy M. Sioussat, Ph.D.

Registration No. 50,609

40 Landsdowne Street

Cambridge, MA 02139

Telephone - 617-374-7679

Facsimile - 617-551-8820

Please	type a	plus	sian	(+)	inside	this	box	-
· icusc	type a	piuo	0.9.	<b>۱'</b>				

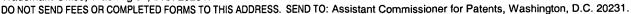
PTO/SB/08B (10-96)

Approved for use through 10/31/99. OMB 0654-0031 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Papen	work Redu	action Act of 1995, no pe	ersons are required	to respond to a	collection of info	rmation unless it con	tains a valid OMB control number.		
Substitute fo	r form 1	449B/PTO	OC7	2 6 2006		Con	nplete if Known		
INIEGE	A A A	TION DIO			Applicati	on Number	10/728,055		
	KIVIA	TION DIS	CLOS		Filing Da		December 4, 2003		
STATE		NT BY AF	PPLICAR			ed Inventor	George Mulligan		
OIAIL	_171L		i Lio/ti	<b>v</b> .	Group Art		1642		
	(1100	aa many ahaata aa	noooccan/)				Reddig, Peter J.		
Chaot	(use	as many sheets as of	necessary)		Examiner Name Reddig, Peter J.  Attorney Docket Number MPI02-202P1RNM				
Sheet	1		D DDIOD ADT	NON DA		RATURE DOC			
							(when appropriate), title of the item	$\overline{}$	
Examiner Initials*	Cite No. <sup>1</sup>			symposium	, catalog, etc		volume-issue number(s), publisher,	T <sup>2</sup>	
	C1	Adams, Julian,	et al., "Proteas				nt and Effective Antitumor	1	
		Agents," Cance							
	C2 .	Adams, Julian, 9-16	Adams, Julian, "Development of the Proteasome Inhibitor PS-341," <i>The Oncologist</i> , Vol. 7 (2002) pp 9-16						
								↓	
	C3	Lightcap, Eric S., et al., "Proteasome Inhibition Measurements: Clinical Application," <i>Clinical Chemsitry</i> , Vol. 46, No. 5 (2000) pp 673-683							
	C4	Hochwald, Steven N., et al., "Antineoplastic Therapy in Colorectal Cancer through Proteasome Inhibition," <i>The American Surgeon</i> , Vol. 69 (January 2003) pp 15-23  Richardson, Paul G., et al., "A Phase 2 Study of Bortezomib in Relapsed, Refractory Myeloma," <i>The New England Journal of Medicine</i> , Vol. 348, No. 26 (June 26, 2003) pp 2609-2617							
	<b>C</b> 5								
	van de Vijver, Marc J., et al., "A Gene-Expression Signature as a Predictor of Survival in Breast Cancer," <i>The New England Journal of Medicine</i> , Vol. 347, No. 25 (Dec. 19, 2002) pp 1999-2009								
	C7	Barden, Catherine B., et al., "Classification of Follicular Thyroid Tumors by Molecular Signature: Results of Gene Profiling," Clinical Cancer Research, Vol. 9 (May 2003) pp 1792-1800							
	C8	Jiang, Xiaoyan, et al., "Ahi-1, a Novel Gene Encoding a Modular Protein with WD-40-Repeat and SH3 Domains, Is Targeted by the Ahi-1 and Mis-2 Provirus Integrations," Journal of Virology, Vol. 76, No. 18 (Sept. 2002) pp 9046-9059							
	C9	Jiang, Xiaoyan, et al., "Deregulated Expression in Ph+ Human Leukemias of <i>AHI</i> -1, a Gene Activated by Insertional Mutagenesis in Mouse Models of Leukemia," <i>Blood</i> , Vol. 103, No. 10 (May 15, 2004) pp 3897-3904							
Examiner						Date			

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231.

Considered



Signature

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation design number. <sup>2</sup>Applicant is to place a check mark here is English language Translation is attached.